

## TITLE OF THE INVENTION

### CRYOCOOLER WITH OIL LUBRICATED COMPRESSOR

## BACKGROUND OF THE INVENTION

### FIELD OF THE INVENTION

[0001] This application is a 35 USC 119(e) non-provisional of U.S. Provisional Application Serial No. 60/465,175 filed April 23, 2003. The disclosure of the provisional application is incorporated herein by reference. The present invention relates generally to cryocoolers and more particularly to cryosurgery including cryoablation using a cryocooler.

### DESCRIPTION OF THE RELATED ART

[0002] The use of freezing temperatures for the therapeutic destruction of tissue began in England in the mid 1800s. See History of Cryosurgery, Gage, A., Seminars in Surgical Oncology 1998; 14:99-109 and Cryosurgery, Rubinsky, B., Annual Review of Biomedical Engineering 2000, 02:157-87. One application of cyrosurgery is endometrial ablation which is ablation of tissue of the inner layer of the uterine wall. Joule-Thomson (hereinafter "JT") cryocoolers can be either open or closed loop systems suitable for use in cryosurgical applications such as endometrial ablation. The closed loop systems can be either single or dual compressor systems.

[0003] U.S. patent No. 5,758,505 to Dobak et al. describes a dual loop system and is incorporated in its entirety herein by reference. Figure 1 is a schematic illustration of a closed JT based cryocooler having a primary loop 100 and a secondary loop 200. The system includes first and second primary heat exchangers 140 and 160, respectively, primary/secondary heat exchanger 240, primary and secondary compressors 130 and 230, respectively, and primary and secondary expansion elements 150 and 250.

[0004] The primary loop includes the primary compressor 130 which compresses a primary gas mixture to a selected pressure and temperature. The primary compressor does not require oil. The high pressure primary gas mixture flows from an outlet of the primary compressor

130, through the first primary heat exchanger 140, which can be a miniature heat exchanger located in the handle of a cryoprobe. Specifically, the high pressure primary gas mixture passes through a high pressure passageway of the first primary heat exchanger 140, where it is cooled to a lower temperature.

[0005] The high pressure gas mixture then passes through the primary/secondary heat exchanger 240, specifically through a high pressure primary passageway of the primary/secondary heat exchanger 240, where it is further cooled to a lower temperature. The high pressure primary gas mixture then passes through a second primary heat exchanger 160, specifically through a high pressure passageway of the second primary heat exchanger, where it is still further cooled.

[0006] The gas mixture then flows to the primary JT expansion element 150. After isenthalpic expansion in the primary expansion element 150 the expanded low pressure gas mixture cools target tissue T.

[0007] Then, the low pressure primary gas mixture passes back through a low pressure passageway in the second primary heat exchanger 160, where it is warmed and through a low pressure passageway in the first primary heat exchanger 140, where it is warmed even further. The low pressure gas mixture then returns to an inlet of the primary compressor 130.

[0008] The secondary loop 200 includes a high pressure path and a low pressure path. The secondary loop compressor 230 compresses the secondary refrigerant to a pressure which can be relatively higher than the pressure found in the primary system, since the secondary system does not enter the cannula of the probe. The high pressure secondary refrigerant then flows from an outlet of the secondary compressor 230, through the primary/secondary heat exchanger 240, which can also be a miniature heat exchanger located in the handle of the cryoprobe. Specifically, the high pressure secondary refrigerant passes through a secondary

high pressure passageway of the primary/secondary heat exchanger 240, where it is cooled to a lower temperature.

[0009] The high pressure secondary refrigerant then passes through a secondary JT expansion element 250. After isenthalpic expansion in the secondary expansion element 250, the expanded low pressure secondary refrigerant passes back through a low pressure passageway in the primary/secondary heat exchanger 240. The low pressure secondary refrigerant then returns to an inlet of the secondary compressor 230.

[0010] A problem with this prior art dual loop system is that it is very sensitive to blockage of the expansion element 150 by freezing of vapor or liquid contaminants. Oil used in a typical commercial refrigeration compressor is such a contaminant and has a freezing point of approximately minus 80 degrees Celsius. In order to avoid blockage due to oil contaminant, some prior art systems such as the Dobak system resort to an oil-less compressor; however, those systems prove to be costly and complex.

[0011] Single compressor (oil) closed loop systems are also known. These systems also suffer from blockage in the expansion element due to freezing of oil contaminants originating in the oil compressor. Further, in a single loop system, there is an inability to phase in operation of the dual cooling loops in order to reduce the chance of contaminants creating a blockage.

#### SUMMARY OF THE INVENTION

[0012] In view of the above, it is an object of the present invention to provide single and dual loop refrigeration systems using inexpensive oil compressors without the side-effect of blockage at the primary expansion element.

[0013] The present invention achieves this goal by using a refrigerant which is a solvent of the contaminant oil.

**[0014]** The present invention further achieves this goal using a dual loop cooling system including a primary loop including a first oil compressor configured to raise the pressure of a gas mixture flowing through the primary loop, an oil separator configured to separate oil contaminant from the gas mixture, a valve configured to return the separated oil back to the first oil compressor when the valve is in an open state, at least one heat exchanger, and a first expansion element. The cooling system further includes a secondary loop including a primary/secondary heat exchanger. The primary/secondary heat exchanger also forms a part of the primary loop. The gas mixture includes constituents (i) that function as a solvent of the oil contaminant which fail to be separated from the refrigerant by the oil separator and (ii) that at least substantially condense in the primary/secondary heat exchanger.

**[0015]** Alternatively, the present invention achieves this goal using a single compressor system including an oil compressor configured to raise the pressure of a gas mixture; an oil separator configured to separate oil contaminant from the gas mixture; a first valve configured to return the separated oil back to the oil compressor when the valve is in an open state; a condenser configured to change the phase of the gas mixture from vapor to a vapor and liquid combination; a phase separator configured to separate the liquid from the vapor; and a probe including a first heat exchanger and a second heat exchanger. The gas mixture includes constituents (i) that function as a solvent of the oil contaminant which fail to be separated from the gas mixture by the oil separator and (ii) that at least substantially condense in the pre-cooler.

**[0016]** The present invention also achieves the goal of reducing blockage at the primary expansion element in a dual loop system by starting operation of the secondary compressor in order to bring the primary/secondary heat exchanger to a predetermined operating temperature; and starting operation of the primary compressor after the primary/secondary heat exchanger has reached its predetermined operating temperature.

[0017] The present invention also achieves the goal of reducing blockage at the primary expansion element in a single compressor system by closing a valve in order to bring a primary/secondary heat exchanger to a predetermined operating temperature. Then, after the primary/secondary heat exchanger has reached its predetermined operating temperature, the valve is opened in order to allow the refrigerant to reach the primary expansion element via the primary/secondary heat exchanger.

[0018] Lastly, the present invention achieves the goal of reducing blockage at the primary heat exchanger by vacuum baking the primary compressor without any oil therein at a predetermined temperature for a predetermined time period; and assembling the cryosurgical system including the baked primary compressor.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0019] A more complete appreciation of the invention and many of the attendant advantages thereof will be readily obtained as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

[0020] Figure 1 illustrates a prior art dual loop system;

[0021] Figure 2 is a schematic illustration of a dual loop system according to the present invention;

[0022] Figure 3 is a pressure enthalpy diagram for the system of the Figure 1;

[0023] Figure 4 is a schematic illustration of a single loop system according to the present invention;

[0024] Figure 5a is a flowchart showing the steps for starting operation of the dual loop system according to an embodiment of the invention;

[0025] Figure 5b is a flowchart showing the steps for starting operation of the single compressor system according to an embodiment of the invention; and

[0026] Figure 6 is a flowchart showing the steps for reducing the contaminants of a compressor prior to assembling a cryocooler system according to the present invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0027] Referring now to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views. Figure 2 is a schematic illustration of a closed JT based cryocooler having a primary loop 6 and a secondary loop 8. The system includes primary heat exchanger 24, primary/secondary heat exchanger 22, primary and secondary compressors 2 and 4, respectively, and primary and secondary expansion elements 26 and 28.

[0028] The primary loop includes the primary compressor 2 which compresses a primary gas mixture to a selected pressure and temperature. The selected pressure is approximately 365 psia. The primary compressor is an oil lubricated compressor such as Danfoss model TLS4.5FCLX. Oil lubricated compressors are known to place oil contaminants in the gas mixture of its high pressure output. The high pressure primary gas mixture flows from an outlet of the primary compressor 2, through an oil separator 10. The oil separator 10 can be for example an oil separator from Temprite model #320. The oil separator 10 removes most of the oil contaminants, approximately 99 percent, from the gas mixture and returns the oil contaminants to the input of the primary compressor 2 via a valve 12. In a preferred embodiment, the valve 12 is a solenoid valve. The solenoid valve is not a flow restrictor such as a capillary, but rather is a mechanism which has an open and closed state. According to an embodiment of the invention, the solenoid valve is opened during startup of the compressor 2 for about 5 seconds and is closed thereafter.

[0029] A second output of the oil separator provides the high pressure primary gas mixture to the primary/secondary heat exchanger 22 (i.e., a pre-cooler heat exchanger) via a high pressure primary passageway provided in flexline 18. The high pressure gas mixture is at

room temperature upon exiting the oil separator 10 and entering the flex line 18. The flexline 18 is a flexible conduit enclosing the fluid and electrical lines between a console 16 and a probe 20. The primary/secondary heat exchanger 22 cools the gas mixture to a lower temperature, approximately minus 40 degrees Celsius. The gas mixture is selected so as to fully or partially condense in the primary/secondary heat exchanger. At least 20 percent of the gas mixture should condense. Further, the constituents of the gas mixture are selected so that the condensate is a solvent of the oil used by the compressor 2. In a preferred embodiment, the constituents of the gas mixture include R116 ( $C_2F_6$ ). The high pressure primary gas mixture then passes through a primary heat exchanger 24 (i.e., a recuperator heat exchanger), specifically through a high pressure passageway of the primary heat exchanger 24, where it is still further cooled to a lower temperature of approximately minus 80 degrees Celsius.

[0030] The gas mixture then flows to the primary JT expansion element 26. After isenthalpic expansion in the primary expansion element 26, the expanded low pressure gas mixture cools target tissue 30. Because the oil which reaches the primary expansion element 26 is already in a very dilute solution with condensed refrigerants, the likelihood of the expansion element 26 becoming blocked is reduced significantly.

[0031] Then, the low pressure primary gas mixture passes back through a low pressure passageway in the primary heat exchanger 24. The low pressure gas mixture then returns to an inlet of the primary compressor 2.

[0032] The secondary loop 8 includes a high pressure path and a low pressure path. The secondary loop compressor 4 compresses the secondary refrigerant to a pressure of approximately 300 psia. According to one embodiment, the secondary refrigerant is R410a. The high pressure secondary refrigerant then flows from an outlet of the secondary compressor 4, through a condenser 14. The condenser 14 changes the secondary refrigerant

from a superheated vapor to a sub-cooled liquid. The high pressure secondary refrigerant then flows from the outlet of the condenser through the flexline 18.

[0033] The high pressure secondary refrigerant then passes through a secondary expansion element 28. After isenthalpic expansion in the secondary expansion element 28, the expanded low pressure secondary refrigerant passes back through a low pressure passageway in the primary/secondary heat exchanger 22. The low pressure secondary refrigerant then returns to an inlet of the secondary compressor 4.

[0034] The primary compressor 2, the secondary compressor 4, the oil separator 10, the solenoid valve 12, and the condenser 14 are all housed in console 16. Whereas, the primary/secondary heat exchanger 22, the primary heat exchanger 24, the primary JT expansion element 26, and the secondary JT expansion element 28 are located in the probe 20. In one embodiment, the console 16 is approximately 72 kilograms and 66x36x69 cm<sup>3</sup>. The probe 20 includes a disposable portion which attaches to the distal end of the probe 20 and provides a sterile cover for the probe 20. Only the tip of the disposable probe causes freezing of tissue. The disposable probe is a sterile, single use device suitable for intrauterine placement and tissue ablation. It has heating capability for thaw cycles to allow probe removal. The disposable probe includes thermocouples to monitor the tip and catheter temperatures. The disposable probe includes an injection port and lumens which allow saline solution to be injected into the patient. The entire contents of the August 13, 2003 Specification, Her Option Cryoablation Therapy System is incorporated herein by reference.

[0035] The gas mixture of the primary loop has a freezing point below the lowest temperature of the primary cycle which is approximately minus 130 degrees Celsius and therefore does not cause blockage of the primary expansion element 26. To make this most effective, it is beneficial to phase the operation of the primary and secondary compressors.

That is, according to a method of operation shown in Figure 5a, the secondary compressor 4 is started in order to bring the primary/secondary heat exchanger 22 to a predetermined operating temperature of minus 50 degrees Celsius in step 100. Then, after the primary/secondary heat exchanger 22 has reached its predetermined operating temperature, operation of the primary compressor 2 is begun in step 110. This reduces the chance of blockage at the primary compressor 24 due to frozen contaminants in the gas mixture of the primary loop. Figure 3 illustrates the pressure enthalpy diagram for such a system.

[0036] Fig 4 illustrates a single compressor system according to an embodiment of the invention. Similar to the dual loop system of Figure 2, the single compressor system includes a compressor 2, oil separator 10, and valve 12. The compressor is an oil lubricated compressor such as Danfoss model TLS4.5F. As discussed above, oil lubricated compressors are known to place oil contaminants in the gas mixture of its high pressure output. The high pressure primary gas mixture flows from an outlet of the compressor 2, through an oil separator 10. The oil separator 10 can be for example an oil separator from Temprite model #320. The oil separator 10 removes most of the oil contaminants, approximately 99%, from the gas mixture and returns the oil contaminants to the input of the compressor 2 via a valve 12. In a preferred embodiment, the valve 12 is a solenoid valve. The solenoid valve is not a flow restrictor such as a capillary, but rather is a mechanism which has an open and closed state. According to an embodiment of the invention, the solenoid valve is opened for about 5 seconds and is closed thereafter.

[0037] A second output of the oil separator provides the high pressure primary gas mixture to the condenser 14. The condenser 14 changes the secondary refrigerant from a superheated vapor to a sub-cooled liquid. The high pressure refrigerant which is a mixture of liquid secondary refrigerant and vapor primary refrigerant at this point then flows from the outlet of the condenser 14 to a phase separator 32. The phase separator 32 has two outputs. A first

output provides a high pressure gas to a valve 34. The second output provides the refrigerant in a liquid state to the secondary JT expansion element 28 via flexline 18.

[0038] According to an embodiment of the present invention, the valve 34 is a solenoid valve. Similar to the method of operation described above, according to an embodiment of the invention illustrated in Figure 5b, during initial operation of the system, the valve 34 is closed in step 150. The valve 34 is closed in order to bring the primary/secondary heat exchanger 22 to a predetermined operating temperature of minus 50 degrees Celsius without simultaneous operation of the primary heat exchanger. Then, after the primary/secondary heat exchanger 22 has reached its predetermined operating temperature, the valve 34 is opened in order to allow the refrigerant to reach the primary heat exchanger 24 via the primary/secondary heat exchanger 22 in step 160. This method of operation reduces the chance of blockage at the primary expansion element 26 due to frozen contaminants.

[0039] After the valve 34 is opened, the primary/secondary heat exchanger 22 cools the high pressure gas mixture to a lower temperature of approximately minus 40 degrees Celsius. The gas mixture is selected so as to fully or partially condense in the primary/secondary heat exchanger 22. Further, the constituents of the gas mixture are selected so that the condensate is a solvent of the oil used by the compressor 2. In a preferred embodiment, the constituents of the gas mixture include R116 ( $C_2F_6$ ). The high pressure primary gas mixture then passes through a first primary heat exchanger 24, specifically through a high pressure passageway of the primary heat exchanger 24, where it is still further cooled to a lower temperature.

[0040] The gas mixture then flows to the primary JT expansion element 26. After isenthalpic expansion in the primary expansion element 26, the expanded low pressure gas mixture cools target tissue 30. Because the oil which reaches the primary expansion element 26 is already in a very dilute solution with condensed refrigerants, the likelihood of the expansion element 26 becoming blocked is reduced significantly.

[0041] Then, the low pressure primary gas mixture passes back through a low pressure passageway in the primary heat exchanger 24. The low pressure gas mixture then returns to an inlet of the primary compressor 2.

[0042] The second output of the phase separator 32 provides the refrigerant in a liquid state to the secondary expansion element 28 via flexline 18. After isenthalpic expansion in the secondary expansion element 28, the expanded low pressure secondary refrigerant passes back through a low pressure passageway in the primary/secondary heat exchanger 22. The low pressure secondary refrigerant then returns to an inlet of the compressor 2.

[0043] The compressor 2, the oil separator 10, the valve 12, the condenser 14, the phase separator 32, and the valve 34 are all provided in the console 16. Whereas, the primary/secondary heat exchanger 22, the primary heat exchanger 24, and the primary and secondary expansion elements 26 and 28 are provided in the probe 20. All of the components provided in the console operate at room temperature or hotter, up to approximately 80 - 90 degrees Celsius. Hence, the flexline 18 does not require insulation in order to transport the refrigerant to and from the probe 20.

[0044] In order to further reduce the amount of contaminants in the refrigerant due to the oil of the primary compressor, according to an embodiment of the invention illustrated in Figure 6, the primary compressor is vacuum baked without any oil therein at a predetermined temperature for a predetermined time period in step 200 prior to assembling the cryosurgical system including the baked primary compressor in step 250.

According to an embodiment of the invention, the predetermined temperature for baking the compressor is 100 degrees Celsius and the predetermined time period for baking is approximately one week. The specific duration of baking is determined by measuring when the contaminants reach a predetermined low level.

[0045] Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.